**DEPARTMENT OF THE ARMY**
**US ARMY CHEMICAL MATERIALS AGENCY**
**5183 BLACKHAWK ROAD**
**ABERDEEN PROVING GROUND MD 21010-5424**

REPLY TO
ATTENTION OF

AMSCM-RD

10 December 2004

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Exemption #CMA-HD-02, Use of M40-series Mask in Mustard Operations

1. Subject exemption is enclosed for your consideration and use as desired. The exemption authorizes use of the M40-series mask in sulfur mustard operations up to the maximum use concentrations specified. When applied to a sulfur mustard operation, this exemption supersedes the US Army Chemical Materials Agency (CMA) *Monitoring Concept Plan* and other CMA documents that reiterate Army restrictions on use.

2. The exemption is expected to mitigate the impact of the new airborne exposure limits while maintaining maximum workforce protection.

3. Point of contact for this transmittal is Mr. Carl T. Anderson, telephone (410) 436-3871 or e-mail Carl.T.Anderson@us.army.mil.

Encl

GREGORY W. ST. PIERRE
Director, Risk Management

DISTRIBUTION:
All CMA Project/Product Managers
All CMA Commanders
All CMA Site Project Managers
All CMA Safety Office

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**EXEMPTION # CMA-HD-02:**

**USE OF M40-SERIES MASK IN SULFUR MUSTARD (H/HD/HS/HT) OPERATIONS**

APPROVED/DISAPPROVED: ______________________ DATE: 29 NOV 2004

MICHAEL A. PARKER
Director

CONCUR/NONCONCUR: ______________________ DATE: 15 Nov 04

GREGORY W. ST. PIERRE
Director, Risk Management

PREPARED BY: ______________________ DATE: 10 Nov 04

CARL T. ANDERSON, CSP
Chief, Safety Office

# EXEMPTION # CMA-HD-02: USE OF M40-SERIES MASK IN SULFUR MUSTARD (H/HD/HS/HT) OPERATIONS

1. **References.** See Appendix A, *References.*

2. **Authority**. The Director, US Army Chemical Materials Agency (CMA) has authority to approve any exemption with *medium* or *low* risk. [Reference 8, Paragraph 2; and Reference 11, Paragraph 3-3b.]

3. **Purpose**. This exemption authorizes CMA organizations and contractors to use the M40-series mask for respiratory protection in sulfur mustard (H/HD/HS/HT) operations. Any organization or contractor applying this exemption to its operations shall maintain a copy on file in its Safety Office.

4. **Scope**.

a. This exemption is specific to the M40-series mask. It does not apply to commercially available respirators. The National Institute for Occupational Safety and Health (NIOSH) maintains a list of NIOSH-approved respirators and restrictions on use. The US Army Edgewood Chemical Biological Center (ECBC) maintains a list of Army-approved respirators and restrictions on use. Those who would like to use a commercially available respirator should obtain copies of the approval and restrictions on use from NIOSH or ECBC.

b. This exemption is specific to sulfur mustard operations. It does not apply to nitrogen mustard operations.

5. **Background.**

a. For more than 20 years NIOSH recommended that occupational exposures to carcinogens be limited to the lowest feasible concentration. Where respiratory protection was used, NIOSH recommended that only the most reliable and most protective respirators be used—that is, self-contained breathing apparatus (SCBA) or supplied-air respirator (SAR) with an auxiliary SCBA. Other respirators—that is, air-purifying respirator (APR) and SAR without an auxiliary SCBA—were not recommended. [Reference 5, Appendix A.]

b. NIOSH policy changed in 1997. NIOSH now recommends the complete range of respirators for carcinogens with quantitative exposure limits based on all health effects, including carcinogenicity. Exposure limits for some carcinogens are not quantitative ("lowest feasible concentration") or are based on technological limits (for example, formaldehyde, benzene, and ethylene oxide). Where a quantitative exposure limit based on all health effects is not available, NIOSH still recommends an SCBA or SAR with an auxiliary SCBA. [Reference 5, Appendix A; and Reference 7, Page 54.]

c. Current Army chemical agent safety standards implement the old NIOSH recommendations, not the new NIOSH recommendations. Where sulfur mustard concentrations exceed the airborne exposure limit, Army standards still require workers to use an SCBA or SAR with an auxiliary SCBA. Army standards allow an APR to be used for escape purposes only. [References 11-13.]

d. This exemption relies on the new NIOSH recommendations, Centers for Disease Control (CDC)-recommended airborne exposure limits, and cancer risk estimates reported by the US Army Center for Health Promotion and Preventive Medicine. [References 3, 5, and 7.]

6. **Specific Deviation from Army Requirements.**

a. This exemption does not affect any Occupational Safety and Health Administration (OSHA) standard. Army Regulation (AR) 385-10, *Army Safety Program*, paragraph 3-5 prohibits commanders from approving deviations from OSHA standards.

b. This exemption applies to requirements found in AR 385-61.

(1) Paragraph 2-5g states, "SCBA or combination airline respirator with auxiliary self-contained air supply are required for entries into environments above the maximum use concentrations (APRs) listed in Table 2-2 with Note 3."

Table 2-2 specifies that 0.003 $mg/m^3$ is the maximum use concentration for chemical agent H/HD. The table notes explain that the maximum use concentration is low because of concerns about carcinogenicity.

(2) Paragraph 2-5m states, "Mustard agent workers conducting operations in H areas where concentrations exceed 0.003 $mg/m^3$ as the airborne exposure limit must wear a NIOSH/MSHA-approved pressure-demand, full-facepiece SCBA or SAR."

c. This exemption also applies to requirements found in the Army's implementation guidance for the new airborne exposure limits. [Reference 13.]

(1) Paragraph 8f states, "Use of M40 Mask with H, HD, and HT. The M40 Mask may be used for escape from environments containing concentrations above the STEL. The M40 mask may be used for routine entry with real-time monitoring for STEL and historical monitoring for the WPL. The M40 mask will not be used for routine respiratory protection above the STEL or in the absence of WPL monitoring."

7. **Reason for Deviation.** Where sulfur mustard concentrations are known (or reasonably expected) to exceed the airborne exposure limit, workers require respiratory protection. Based on Army requirements, workers must use SCBA or SAR with an auxiliary SCBA. This provides maximum respiratory protection but may reduce overall safety.

a. The physiological burden on workers is greatly increased. For example, heat stress is much more likely with SCBA or SAR than with an APR. Heat stress can lead to unconsciousness and in severe cases cardiac arrest.

b. Agility is greatly reduced. The SCBA and SAR typically weigh much more than an APR. This additional weight shifts a worker's center of gravity and makes him more likely to lose his balance. A maintenance worker is especially prone to falling as he reaches, extends, and climbs to perform his duties.

c. The SCBA and SAR are typically bulkier than the APR. This makes it more difficult for workers to pass through tight spaces and more likely that workers will be snagged or caught on equipment, pallets, etc. This could damage protective clothing and equipment.

d. Time to respond to the scene of an emergency is greatly increased. The SCBA and SAR typically require more time to don than the APR does. Casualties may wait longer for rescue and medical attention. Accident scenes may remain dangerous longer before they are returned to a safe and stable condition.

e. Mission time may be greatly reduced. For example, workers running a decontamination line ("hotline") cannot remain at their stations longer than their air supply lasts. Workers must rotate on and off duty frequently so that personnel exiting the contaminated area can be decontaminated. Once all air supplies have been exhausted, there is no respiratory protection approved by the Army that the workers could use in the decontamination line.

8. **Corrective Action Plan and Schedule.**

a. APR use in sulfur mustard operations was discussed in electronic mail messages exchanged between the Mr. Proper, Army Safety Office, Ms. Maggio, Project Manager for Chemical Stockpile Disposal (PMCSD) Operations Team, and Mr. Anderson, CMA Safety Office on 16 - 17 June 2004. Mr. Proper stated that the issue would be considered when AR 385-61 and Department of Army Pamphlet (DA PAM) 385-61 were updated.

b. APR use in sulfur mustard operations was discussed again in electronic mail messages exchanged among Mr. Proper, Ms. Christie, US Army Materiel Command (AMC) Safety Office), and Mr. Anderson on 11 – 18 August 2004. Mr. Proper again stated that the issue would be considered when AR 385-61 and DA PAM 385-61 were updated.

c. On 4 November 2004, the Department of the Army Chemical Agent Safety Council discussed APR use in sulfur mustard operations. Mr. Proper, Ms. Christie, and Mr. Dries (Office of the Deputy Assistant Secretary of the Army for the Environment, Safety and Occupational Health) participated in this discussion. Mr. Dries stated that the issue would be addressed when AR 385-61 and DA PAM 385-61 were updated.

d. Based on these exchanges with higher headquarters, the Army is expected to address APR use in sulfur mustard operations when AR 385-61 and DA PAM 385-61 are updated. Because the Army is moving away from military-unique requirements and toward general industry practices, the updated regulation and pamphlet are expected to implement the new NIOSH recommendations.

e. This exemption remains in effect until the Army updates AR 385-61 and DA PAM 385-61 to address the new NIOSH recommendations. This exemption expires on the date specified for implementation of the updated regulation and pamphlet.

9. **Risk Mitigation Measures.** Specific control measures must be implemented to apply this exemption. These control measures are not new since federal and military regulations already require them. They are emphasized here only because they are critical to the validity of the risk assessment below.

a. M40-series mask use is subject to a respiratory program as specified in 29 CFR 1910.134, *Respiratory Protection*, and AR 11-34, *Army Respiratory Protection Program.*

(1) AR 385-61, paragraph 1-4s(11) states, "[Commanders with custody of chemical agents or munitions will] maintain a respiratory protection program for military protective ensembles and masks in accordance with AR 11-34 and national consensus standards. Minimal requirements must include proper selection and use (related to potential workplace exposure levels), training, fit testing, maintenance, storage, and medical clearance."

(b) 68 FR 34114, paragraph X.2, Note to Paragraph (d)(3)(i)(A) states, "The assigned protection factors listed in Table I are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance, and use requirements…."

b. Quantitative fit testing is used for the M40-series mask.

(1) AR 385-61, paragraph 2-5h states, "All personnel issued respiratory protective devices will be fit tested. Quantitative fit testing is the preferred method for all masks and must be used for the M40-series mask…."

(2) DA PAM 385-61, paragraph 4-6d(2)(c) states, "Quantitative fit testing. Test procedures can be found in the latest revision of the M41 operator's manual for the Protective Assessment Test System. Quantitative fit testing must be used for the M40-series mask."

c. The minimum acceptable fit factor for the M40-series mask is 500. The quantitative fit factor 3000, commonly used in the Army, exceeds this requirement.

(1) 29 CFR 1910.134(f)(7) states, "If the fit factor, as determined through an OSHA-accepted quantitative fit test protocol, is…equal to or greater than 500 for tight-fitting full facepieces, the quantitative fit test has been passed with that respirator."

(2) American National Standards Institute standard Z-88.2-1992, *American National Standard for Respiratory Protection*, paragraph 9.1.1 states, "If a quantitative fit test is used, a fit factor that is at least 10 times greater than the assigned protection factor…of a negative-pressure respirator shall be obtained before that respirator is assigned to an individual."

d. Each user is fit tested prior to initial use of the M40-series mask, after modification of the facepiece, after an extended period without use, and at least annually thereafter.

(1) 29 CFR 1910.134(f)(2) states, "The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter."

(2) Technical Manual 3-4240-346-10, Table 2-1 states, "Warning: If you have not used your mask for 30 days or more, perform all [preventive maintenance checks and services] prior to using your mask."

(3) Technical Manual 3-4240-346-20&P, paragraph 2-11 requires an annual fit test for the M40A1 mask.

10. **Statement of Residual Risk.**

a. First, the maximum use concentration is calculated for the M40-series mask in sulfur mustard operations. The calculations are based on quantitative estimates of cancer risk.

(1) The term *maximum use concentration* means the maximum atmospheric concentration of a hazardous substance from which an employee is expected to be protected when wearing a respirator. The maximum use concentration is determined by the assigned protection factor of the respirator and the airborne exposure limit of the hazardous substance. The maximum use concentration usually can be determined mathematically by multiplying the assigned protection factor specified for the respirator by the worker population limit, short-term exposure limit, ceiling limit, or any other airborne exposure limit used for the hazardous substance. [68 FR 34114]

(2) In the commentary accompanying its recommended airborne exposure limits, the CDC emphasizes the uncertainty associated with the cancer potency of sulfur mustard. Despite this uncertainty, the CDC believes that current risk management practices in the chemical demilitarization program minimize cancer risk at the recommended airborne exposure limits. Use of the M40-series mask in sulfur mustard operations would be a significant change to current risk management practices. When

consulted about this change, the CDC urged CMA to fully consider the uncertainty associated with the cancer potency and not to rely solely on the recommended airborne exposure limits. [69 FR 24167 and Reference 14]

(3) Maximum use concentrations for the M40-series mask in sulfur mustard operations are calculated in Appendix B, *Calculation of Maximum Use Concentration*. Out of consideration for the uncertainty associated with the cancer potency of sulfur mustard, calculations are based on a worst-case estimate of cancer risk. The maximum use concentration is calculated to be 0.006 mg/m3 (2-hour time weighted average (TWA)). The short-term excursion limit is calculated to be 0.030 mg/m3 (15-minute TWA).

b. Next the hazard severity and hazard probability are determined. These are used to determine the level of risk. Airborne concentrations required to significantly increase cancer risk are much lower than concentrations required for other adverse health effects or escape impairment. Therefore, in order to be a worst-case assessment, this risk assessment is based on the carcinogenicity of sulfur mustard.

(1) AR 385-61 Figure 3-2, *Matrix Criteria*, defines the hazard severity categories. The hazard severity is determined to be *catastrophic (I)*—the most severe category available—based on a worst-case assumption that any cancer incidence is fatal.

(2) AR 385-61 Figure 3-2, *Matrix Criteria*, also defines the hazard probability categories. If every respirator performed perfectly every time it was used, determining the hazard probability would be trivial. In reality, most respirators perform well most of the time, but some respirators do not perform well sometimes. Detailed calculation of the hazard probability is provided in Appendix C, *Calculation of Hazard Probability*. Based on that calculation, the hazard probability is determined to be *unlikely (E)*—the category for the least probable events.

(3) Since the hazard severity is catastrophic (I) and the hazard probability is unlikely (E), the risk level is *medium (3)* per AR 385-61 Figure 3-1, *Decision Authority Matrix*.

11. **Conclusion.**

a. The level of risk for this exemption is medium (3). The Director, CMA has the authority to approve this exemption. This exemption deviates from Army requirements but conforms to OSHA standards and NIOSH recommendations.

b. Based on this exemption, the M40-series mask may be used for respiratory protection in sulfur mustard operations up to the maximum use concentrations:

- 0.0010 $mg/m^3$ (12-hour TWA) in operations up to 12 hours per workday
- 0.0015 $mg/m^3$ (8-hour TWA) in operations up to 8 hours per workday

- 0.003mg/m$^3$ (4-hour TWA) in operations up to 4 hours per workday
- 0.006 mg/m$^3$ (2-hour TWA) in operations up to 2 hours per workday
- 0.030 mg/m$^3$ (15-minute TWA) not to be exceeded during the workday

c. If workers use the M40-series mask in sulfur mustard operations, monitoring at 0.0004 mg/m$^3$ (8-hour TWA) is not required. The M40-series mask provides equivalent protection as long as the maximum use concentrations listed above are not exceeded.

d. If concentration-time exposures exceed the maximum use concentrations listed above, workers using the M40-series mask for respiratory protection are considered potential exposure cases. The potential exposure should be reported and documented like any other potential exposure would be. However, no signs or symptoms of exposure would be expected since the maximum use concentrations are set to protect against theoretical (and highly uncertain) cancer risk, not observable health effects. An appropriate response would be to administratively remove the worker from sulfur mustard operations long enough to offset the exceedance. For example, if the average airborne concentration during a 2-hour operation was 0.012 mg/m$^3$—twice the maximum use concentration—the worker should be barred from sulfur mustard operations the following workday. Safety, industrial hygiene, and/or occupational health professionals can help determine appropriate work restrictions. Other than to protect human safety and health in an emergency, it is not acceptable to intentionally expose workers to concentrations above the maximum use concentration even if the potential exposure will be offset with a few days restricted duty.

# APPENDIX A. REFERENCES

1. American Conference of Governmental Industrial Hygienists, *TLVs® and BEIs®: Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices*, 2004.

2. Centers for Disease Control and Prevention (CDC), *Proposed Airborne Exposure Limits for Chemical Warfare Agents H, HD, and HT (Sulfur Mustard)* (Federal Register, Volume 68, No. 140, Pages 43356-43358), 22 July 2003.

3. CDC, *Interim Recommendations for Airborne Exposure Limits for Chemical Warfare Agents H and HD (Sulfur Mustard)* (Federal Register, Volume 69, No. 85, Pages 24164-24168), 3 May 2004.

4. Environmental Protection Agency, *National Advisory Committee for Acute Exposure Guideline Levels (AEGLs) for Hazardous Substances, Proposed AEGL Values; Notice* (Federal Register, Volume 65, No. 51, Pages 14186-14197), 15 March 2000.

5. National Institute for Occupational Safety and Health (NIOSH), *NIOSH Pocket Guide to Chemical Hazards* (Publication No. 97-140), February 2004.

6. Occupational Safety and Health Administration, *Assigned Protection Factors* (Federal Register, Volume 68, No. 5, Pages 34036-34119), 6 June 2003.

7. US Army Center for Health Promotion and Preventive Medicine (USACHPPM), *Evaluation of Airborne Exposure Limits for Sulfur Mustard: Occupational and General Population Exposure Criteria* (Technical Report 47-EM-3767-00), November 2000.

8. US Army Materiel Command (AMCPE-SF-X), memorandum, subject: Waiver Approval Authority, 9 February 2004.

9. US Department of the Army, *Operator's Manual for Chemical-Biological Mask: Field M40A1 (4240-01-370-3821—Small), (4240-01-370-3822—Medium), (4240-01-370-3823—Large); and Chemical-Biological Mask: Combat Vehicle M42A2 (4240-01-413-4100—Small), (4240-01-413-4101—Medium), (4240-01-413-4102—Large)* (Technical Manual 3-4240-346-10), 1 August 1998.

10. US Department of the Army, *Unit Maintenance Manual for Chemical-Biological Mask: Field M40A1 (4240-01-370-3821—Small), (4240-01-370-3822—Medium), (4240-01-370-3823—Large); and Chemical-Biological Mask: Combat Vehicle M42A2 (4240-01-413-4100—Small), (4240-01-413-4101—Medium), (4240-01-413-4102—Large)* (Technical Manual 3-4240-346-20&P), 1 August 1998.

11. US Department of the Army, *Army Chemical Agent Safety Program* (Army Regulation 385-61), 12 October 2001.

12. US Department of the Army, *Toxic Chemical Agent Safety Standards* (Department of Army Pamphlet 385-61), 27 March 2002.

13. US Department of the Army, *Implementation Guidance Policy for Revised Airborne Exposure Limits for GB, GA, GD, GF, VX, H, HD, and HT*, 18 June 2004.

14. Telephone call including John Decker (CDC), Harvey Rogers (CDC), and Carl Anderson (US Army Chemical Materials Agency), 25 October 2004, subject: Use of M40-Series Mask in Sulfur Mustard Operations.

# APPENDIX B.

# CALCULATION OF MAXIMUM USE CONCENTRATION

1. No single acceptable level of cancer risk has been promulgated. However, one can be inferred from federal regulations and past precedents. The US Supreme Court has stated that individual risk less than $1 \times 10^{-6}$ cancer incidences in a lifetime is negligible. OSHA standards imply a threshold for regulatory action at $1 \times 10^{-3}$ cancer incidences in a lifetime. In its Superfund regulations, the Environmental Protection Agency states that individual risk between $1 \times 10^{-4}$ and $1 \times 10^{-6}$ cancer incidences in a lifetime is acceptable. Past regulatory decisions imply that the number of individuals at risk is an important factor—higher individual risk appears to be appropriate for smaller populations (thousands), and lower individual risk appears to be appropriate for larger populations (millions). [Reference 7, Pages 53-54]

2. An individual risk of $1 \times 10^{-4}$ cancer incidences in a lifetime is appropriate for this exemption because of the relatively small size of the CMA workforce—military, civilian, and contractor. Furthermore, the number of individuals expected to routinely use the M40-series mask in sulfur mustard operations is much smaller.

3. The CDC has recommended airborne exposure limits for sulfur mustard. The CDC believes that cancer risk is minimized at these recommended airborne exposure limits because of current risk management practices in the chemical demilitarization program. However, when consulted about use of the M40-series mask in sulfur mustard operations, the CDC discouraged relying solely on the recommended airborne exposure limits. The CDC urged CMA to adopt an approach that more fully considered the uncertainty associated with the cancer potency of sulfur mustard. [69 FR 24167 and Reference 14]

4. In its evaluation of airborne exposure limits for sulfur mustard, the US Army Center for Health Promotion and Preventive Medicine does excellent work describing the uncertainty associated with the cancer potency of sulfur mustard. Estimates of the inhalation risk range from 0.46 to 120 cancer incidences in a lifetime per $mg/m^3$. Out of consideration for that uncertainty, this exemption uses the highest estimate of inhalation risk. [Reference 7, Table 20]

5. It should be acknowledged that some experts do not believe sulfur mustard increases cancer risk unless the exposure is severe enough to produce other health effects. In its commentary accompanying the proposed acute exposure guideline levels, the Environmental Protection Agency observes, "Sulfur mustard is genotoxic and has induced carcinogenic responses in humans following multiple exposures that were sufficient to produce adverse effects. Carcinogenic responses, however, are not known to occur with asymptomatic exposures." Despite that expert opinion, this risk assessment makes the worst-case assumption that even concentrations too low to cause other health effects may still increase cancer risk. [65 FR 14189]

6. Once an acceptable level of individual risk is selected and an estimate of inhalation risk is selected, the maximum use concentration can be calculated. The calculation includes several important factors.

a. The calculation includes the assigned protection factor (50) currently used for the M40-series mask. If the assigned protection factor were changed, then the maximum use concentration would change proportionally.

b. The calculation assumes the average worker routinely uses the M40-series mask for protection 2 hours per day. The 2 hours is an average: Occasional use more than 2 hours is acceptable as long as it is offset by instances of use less than 2 hours.

c. The calculation assumes the average worker uses the M40-series mask in sulfur mustard operations for 70 months (7 days per week). That is, approximately 2130 workdays total. This is an estimate of the average number of workdays: some workers may actually work more than 2130 days. Days the M40-series mask is not used would not count as workdays for purposes of this calculation. The estimated number of workdays is high compared to current storage and disposal schedules. The high estimate allows for closure activities and for individuals working at more than one site.

7. The maximum use concentration for 2-hours use per workday is calculated as follows:

$$({}^{\text{MUC}} / {}_{50}) \text{ x } (120 \text{ per mg/m}^3) \text{ x } ({}^{2 \text{ hours}} / {}_{24 \text{ hours}}) \text{ x } ({}^{70 \text{ months}} / {}_{70 \text{ years}}) \leq 1 \text{ x } 10^{-4}$$

$$\text{MUC} \leq 0.006 \text{ mg/m}^3 \text{ (2-hour TWA)}$$

8. The 2-hour maximum use concentration is a time-weighted average: short-term excursions are acceptable as long as they are offset by concentrations below the maximum use concentration. Nonetheless, best practices require a limit for short-term excursions. If short-term excursions exceed that limit, workplace conditions are considered to be highly variable, probably unpredictable, and possibly out of control. If data specific to the workplace is available, that data can be used to define a short-term excursion limit. Otherwise, the American Conference of Governmental Industrial Hygienists (ACGIH) recommends specific short-term excursion limits based on variability generally observed in actual industrial processes [Reference 1, Page 5]. This exemption relies on the ACGIH recommendations to define the following short-term excursion limit:

short-term excursion limit (15-minute TWA) = 5 x maximum use concentration

short-term excursion limit = 0.030 mg/m$^3$ (15-minute TWA)

9. Army regulations currently allow use of the M40-series mask in sulfur mustard operations as long as there is monitoring at 0.0004 mg/m$^3$ (8-hour TWA) and near-real-time monitoring at 0.003 mg/m$^3$ (15-minute TWA). Some CMA operations do not have monitoring capability at concentrations as low as 0.0004 mg/m$^3$. For these CMA

operations, it would be helpful to know whether use of the M40-series mask is safe without monitoring at 0.0004 $mg/m^3$. This question can be answered with a calculation similar to the one above:

$$(^{MUC}/_{50}) \text{ x } (120 \text{ per } mg/m^3) \text{ x } (^{8 \text{ hours}}/_{24 \text{ hours}}) \text{ x } (^{70 \text{ months}}/_{70 \text{ years}}) \leq 1 \text{ x } 10^{-4}$$

$$MUC \leq 0.0015 \text{ } mg/m^3 \text{ (8-hour TWA)}$$

Therefore, use of the M40-series mask is safe for a typical workday with monitoring at a concentration well within the range of near-real-time monitoring technology.

# APPENDIX C.

## CALCULATION OF HAZARD PROBABILITY

1. The maximum use concentration calculated in Appendix B protects at a cancer risk level of $1 \times 10^{-4}$ cancer incidences in a lifetime.

2. This risk assessment estimates the cancer risk based on the *actual protection factor*, not the *assigned protection factor*. The *assigned* protection factor is the level of respiratory protection that a respirator is *expected* to provide during routine use. The *actual* protection factor means the level of respiratory protection that a specific respirator *actually* provides on a specific occasion of use. The actual protection factor may be greater than or less than the assigned protection factor.

3. Taking into account the actual protection factor of an M40-series mask, a worker's actual cancer risk can be estimated.

(individual cancer risk) = $(1 \times 10^{-4})$ x
(airborne concentration in the workplace) / (maximum use concentration) x
(<u>assigned</u> protection factor) / (<u>actual</u> protection factor)

For simplicity make a worst-case assumption: airborne concentrations in the workplace are constantly at or near the maximum use concentration. That is, airborne concentrations in the workplace equal the maximum use concentration.

(individual cancer risk) = $(1 \times 10^{-4})$ x 1 x
(assigned protection factor) / (actual protection factor)

(individual cancer risk) = $(1 \times 10^{-4})$ x 1 x 50 / (actual protection factor)

(individual cancer risk) = $(50 \times 10^{-4})$ / (actual protection factor)

4. For illustration purposes, consider the following example. Suppose a worker is using an M40-series mask. To simplify this example, suppose the actual protection factor does not vary and is constantly 40. The worker's cancer risk due to use of the mask is calculated as follows:

(individual cancer risk) = $(50 \times 10^{-4})$ / (actual protection factor)

(individual cancer risk) = $(50 \times 10^{-4})$ / 40

(individual cancer risk) = $1.25 \times 10^{-4}$ cancer incidences in a lifetime

This risk assessment would be trivial if the actual protection factor for the M40-series mask were constant. Since the actual protection factor varies with use, the risk assessment is more difficult. The calculations below take that variability into account.

5. In the commentary accompanying its proposed assigned protection factors, the Occupational Safety and Health Administration describes several tests done to measure the actual protection factors of air-purifying respirators (68 FR 34096-34097). Based on a review of those tests, this risk assessment assumes the actual protection factor for the M40-series mask is a random variable ($x$) distributed as follows:

Region I: Probability$\{1 \leq x < 50\} = 5\%$

Region II: Probability$\{50 \leq x < 100\} = 5\%$

Region III: Probability$\{100 \leq x < 1000\} = 30\%$

Region IV: Probability$\{1000 \leq x < 5000\} = 60\%$

Within each region, the actual protection factor is assumed to vary uniformly. For example, in Region II the actual protection factor is as likely to fall between 50 and 60 as between 75 and 85.

6. With the probability distribution assumed above, a worker's cancer risk can be estimated with some mathematical analysis. The total cancer risk is the sum of four partial cancer risks.

(total cancer risk due to use of the M40-series mask) =

(partial cancer risk attributable to use in Region I) +
(partial cancer risk attributable to use in Region II) +
(partial cancer risk attributable to use in Region III) +
(partial cancer risk attributable to use in Region IV) =

(fraction of uses with actual protection factor in Region I) x
(average cancer risk incurred per use in Region I) +
(fraction of uses with actual protection factor in Region II) x
(average cancer risk incurred per use in Region II) +
(fraction of uses with actual protection factor in Region III) x
(average cancer risk incurred per use in Region III) +
(fraction of uses with actual protection factor in Region IV) x
(average cancer risk incurred per use in Region IV) =

(5%) x (average cancer risk incurred per use in Region I) +
(5%) x (average cancer risk incurred per use in Region II) +
(30%) x (average cancer risk incurred per use in Region III) +
(60%) x (average cancer risk incurred per use in Region IV)

7. The average cancer risk incurred per use in each region can be calculated. This is demonstrated by calculating the average cancer risk incurred per use in Region I.

The average cancer risk can be estimated using basic mathematical concepts. Although this only yields a rough estimate, it illustrates the approach to be used.

(average cancer risk incurred per use in Region I) =

$$[(^{50 \text{ x } 10\text{-}4} /_{1}) + (^{50 \text{ x } 10\text{-}4} /_{2}) + \ldots + (^{50 \text{ x } 10\text{-}4} /_{48}) + (^{50 \text{ x } 10\text{-}4} /_{49})] / 49 =$$

$4.6 \text{ x } 10^{-4}$ cancer incidences in a lifetime (rough estimate)

The average cancer risk can also be calculated using advanced mathematical concepts. The approach is the same as before, but this time it yields an exact solution.

(average cancer risk incurred per use in Region I) =

$$[(^{50 \text{ x } 10\text{-}4} /_{1}) + (^{50 \text{ x } 10\text{-}4} /_{1 + \Delta x}) + \ldots + (^{50 \text{ x } 10\text{-}4} /_{50 - 2\Delta x}) + (^{50 \text{ x } 10\text{-}4} /_{50 - \Delta x})] / (49 / \Delta x) =$$

$$[(^{50 \text{ x } 10\text{-}4} /_{1}) + (^{50 \text{ x } 10\text{-}4} /_{1 + \Delta x}) + \ldots + (^{50 \text{ x } 10\text{-}4} /_{50 - 2\Delta x}) + (^{50 \text{ x } 10\text{-}4} /_{50 - \Delta x})] (\Delta x) / 49$$

As $\Delta x \rightarrow 0$, then (average cancer risk incurred per use in Region I) $\rightarrow$

$$\int_{1 \leq x < 50} (50 \text{ x } 10^{-4} / x)\, dx / 49 = (50 \text{ x } 10^{-4}) [\ln(x) + \text{constant}]_{1 \leq x < 50} / 49 =$$

$(50 \text{ x } 10^{-4}) [\ln(50) - \ln(1)] / 49 = 4.0 \text{ x } 10^{-4}$ cancer incidences in a lifetime

8. Average cancer risks for the other regions are calculated in the same fashion.

(average cancer risk per use in Region II) = $6.9 \text{ x } 10^{-5}$ incidences in a lifetime

(average cancer risk per use in Region III) = $1.3 \text{ x } 10^{-5}$ incidences in a lifetime

(average cancer risk per use in Region IV) = $2.0 \text{ x } 10^{-6}$ incidences in a lifetime

9. With the information above, the total cancer risk can be calculated.

(total cancer risk using M40-series mask) =

(5%) x (average cancer risk incurred per use in Region I) +
(5%) x (average cancer risk incurred per use in Region II) +
(30%) x (average cancer risk incurred per use in Region III) +
(60%) x (average cancer risk incurred per use in Region IV) =

(5%) (4.0 x $10^{-4}$ incidences in a lifetime) +
(5%) (6.9 x $10^{-5}$ incidences in a lifetime) +
(30%) (1.3 x $10^{-5}$ incidences in a lifetime) +
(60%) (2.0 x $10^{-6}$ incidences in a lifetime) =

2.8 x $10^{-5}$ incidences in a lifetime

10. This problem was also modeled through a simple simulation in Microsoft® Excel 2000. Simulation results confirm the analytical result.

11. Therefore, even if airborne concentrations are constantly at the maximum use concentration and respirators don't perform perfectly, workers using the M40-series mask have an acceptable level of cancer risk—less than 1 x $10^{-4}$ cancer incidences in a lifetime.

12. The average number of CMA personnel (military, civilian, and contractor) expected to use the M40-series mask in sulfur mustard operations daily is less than 100. Therefore, the odds *against* any cancer incidence in the workforce (due to this use scenario) are more than 350-to-1.

13. In Figure 3-2, *Matrix Criteria*, of Army Regulation 385-61, *Army Chemical Agent Safety Program*, the hazard probability *unlikely (E)* is defined as "not expected to occur in facility/equipment service life." Based on the calculations above, the hazard probability is determined to be unlikely (E).